REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-18 are pending. Claim 1 is amended to require that the composition be suitable for oral consumption (see page 6, line 13, of the specification). A typographical error in claim 16 is corrected (see page 11, line 19, of the specification).

An Information Disclosure Statement was filed on June 7, 2005 but an initialed Form PTO-1449 was not returned in accordance with M.P.E.P. § 609. Therefore, it is respectfully requested that the Examiner consider the listed documents and confirm his consideration by return of an initialed Form PTO-1449 to make them of record.

Claims 14-16 were rejected under Section 101 because "use" claims which do not set forth any steps involved in the process are allegedly an improper definition of a process. Applicants traverse because claims 14-15 are amended to recite ingesting the composition in the claimed method. This amendment is supported by the originally-filed disclosure at page 18, lines 19 and 27, of the specification. Withdrawal of the Section 101 rejection is requested.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1 and 11-18 were rejected under Section 102(b) as allegedly anticipated by WO 01/00223. Applicants traverse.

WO 01/00223 discloses compositions which might contain insulin and which are administered by a subcutaneous route (page 7, line 33) or by an infusion pump (page 3, line 20). In contrast, the claimed invention requires that the composition be suitable for orally consumption; the pending method claims require ingesting or drinking the composition.

Withdrawal of the Section 102 rejection is requested because all limitations of the claimed invention are not disclosed by the cited reference.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992). It is well established that the mere fact that references can be combined does not render the resultant combination obvious unless the desirability of that combination is also taught or suggested by the prior art. See *In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). Thus, even if all elements of the claimed invention were known, this is not sufficient by itself to establish a prima facie case of obviousness without some evidence that one would have been motivated to combine those teachings in the manner proposed by the Examiner. See *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (B.P.A.I. 1993).

Claims 1-18 were rejected under Section 103(a) as allegedly unpatentable over WO 01/00223 in view of Van Loon et al. (U.S. Patent 6,713,082). Applicants traverse.

The failure of WO 01/00223 to disclose the claimed invention is not remedied by the attempt to combine that disclosure with the cited document. U.S. Patent 6,713,082 (the '082 patent) relates to a composition comprising material which will enhance the blood insulin response after oral intake by humans and is intended for enhanced recovery after or during physical exercise of athletes. See, for example, col. 1, line 29, "athlete" and col. 5, line 65, "trained cyclists." The '082 patent relates to the use of this composition by "healthy" people (see col. 4, line 39) and its objective is to use the composition to enhance the uptake of glucose by muscles and thereby delay exhaustion (col. 4, lines 7-12). So the '082 patent relates to healthy people doing heavy exercise. This in sharp contrast to WO 01/00223 which relates to diabetic patients. Moreover, the

composition of WO 01/00223 would be used to treat diabetes throughout the day and not just after exercise as disclosed in the '082 patent. Therefore, one of ordinary skill in the art would not have been motivated to combine the cited documents because the type of subject, the objective when using the composition, and the length of treatment are so disparate.

Finally WO 01/00223 relates to administering the composition using an infusion pump rather than oral consumption as in the '082 patent. From the above, it is clear that there would be reason to combine the two documents or reasonable expectation of success in administering the composition of the '082 patent in accordance with the parenteral routes disclosed in WO 01/00223 because there is no suggestion to do so or relationship between the documents.

Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claim 18 was rejected under Section 112, first paragraph, because it was alleged that the specification does not reasonably provide enablement for preventing type 2 diabetes. Applicants traverse because claim 18 is clarified to recite "retarding" because we teach that the development of type 2 diabetes with the following use of insulin sensitizers, and then insulin can be postponed (see page 5, lines 29-31, of the specification).

The Examiner did find on page 5 of the Action that the specification was enabling for "treating type 2 diabetes [in a subject in need thereof]." Applicants submit that the

scope of the claims are consistent with this finding of enablement because there is no reason to believe that practicing their invention would require undue experimentation.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

35 U.S.C. 112 – Definiteness

Claims 1-18 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse because claims 14-16 are amended to specify the method being claimed. No objections to claims 1-13 and 17-18 were made in the Office Action so no response is possible.

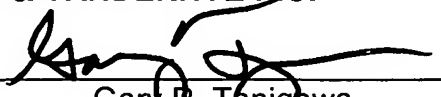
Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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